

PATENT APPLN. NO. 10/786,369  
RESPONSE UNDER 37 C.F.R. §1.111

PATENT  
NON-FINAL

REMARKS

*Oath or Declaration*

The Office notes that PCT/JP98/00351 is listed under the heading "PRIOR FOREIGN APPLICATION(S)" in the declaration filed February 26, 2004, but that a proper box identifying whether or not priority is claimed has not been marked.

The grandparent application, Serial No. 09/355,642, of the present application is a 371 (i.e., national stage) application of PCT/JP98/00351. Priority of the international application under 35 U.S.C. § 119 is not relevant to the present application and nothing is required concerning the boxes identifying whether or not priority is claimed.

*Claim Rejections - 35 USC § 112*

Claims 35 and 37 are rejected in the Action as being indefinite under the second paragraph of 35 U.S.C. § 112 relating to the use of the terms "vaccine" and "vaccine precursor."

The 35 U.S.C. § 112, second paragraph, rejection has been overcome by the above amendments to claim 35 to delete these terms.

Claims 35 and 37 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claim 35 as amended herein (and claim 37) is believed to

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comply with the description requirement of the first paragraph of 35 U.S.C. § 112 for the following reasons.

First, the rejection as it relates to the alleged failure of the specification to include a description such that "one of skilled in the art could reasonable [sic, reasonably] tell what is a vaccine precursor and how the precursor can be use [sic, used] as vaccine for cancer" (Action, page 3, lines 3 and 4 from the bottom of the page) has been overcome by the amendments to claim 35 to delete the terms "vaccine" and "vaccine precursor".

Second, the rejection as it relates to the alleged failure of the experiments in the specification to "clearly show 'prevention' of cancer (i.e. cancer from occurring) or the substance (composition) used as prophylaxis for prevention of cancer in a healthy animal" (Action, page 4, lines 3-5 from the bottom of the page), has been avoided by the amendments to claim 35 to limit the method of the invention to therapy of a cancer in an animal.

Third, the rejection as it relates to the alleged failure of the specification to "provide any clear guidance as to what core component of the compounds [of formula 3-a] is actually having activity responsible" (Action, page 6, lines 6-8) for inhibiting cancer cell growth, i.e., the effect of the compounds other than Yoshixol, has been overcome by the amendments to claim 35 to delete

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a part of the alternatives concerning the substituents R3 to R6 of the Formula 3-a. (It is noted that in claim 35 as amended, R3 to R6 in Formula 3-a are monovalent substituents. Therefore, R3 to R6 cannot be C1 alkylene group (i.e. =CH<sub>2</sub>) and the recitation "C1-C6 alkylene group" has been amended to "C2-C6 alkylene group").

By the amendment to claim 35, the compound of the Formula 3-a is restricted to Yoshixol or a polycyclic compound Yoxhixol-7001, which the Applicant has already demonstrated to have a therapeutic effect on cancer, and to compounds having a structure reasonably similar thereto.

In view of the structural similarity of the compounds, applicants submit that a person of ordinary skill in the art would expect the compounds to exhibit similar effects and that, therefore, amended claim 35 is properly supported by the data for Yoshixol and Yoshixol-7001.

Fourth, regarding the rejection as it relates to the recitation in claims 35 and 37 of the therapy of "cancer", applicants are submitting herewith a declaration under 37 C.F.R. § 1.132 of the inventor Shozo KOYAMA. The declaration includes additional experimental data which show that Yoshixol is useful for the treatment of mesothelioma, which is totally different from leukemia and melanoma. Further, leukemia and melanoma are also

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totally different from each other.

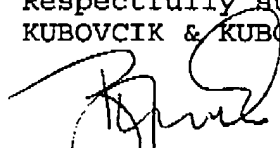
Applicants respectfully submit that data demonstrating the effect of the compounds of the invention on leukemia, melanoma and mesothelioma, which are totally different from each other, supports a conclusion that the present invention is useful for the therapy of various types of cancer.

Removal of the 35 U.S.C. § 112 grounds of rejection is believed to be in order and is respectfully solicited.

The foregoing is believed to be a complete and proper response to the Office Action dated October 8, 2008.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension and any additional required fees may be charged to Deposit Account No. 111833.

Respectfully submitted,  
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Attachment: Declaration under 37 C.F.R. § 1.132 of Shozo KOYOMA